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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,588

Applicant(s)

AFFRIME ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-23, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 1-18, 24-28 and 31-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

Claims 1-59 are presented for prosecution on the merits.

Priority

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Claim Objections

2. Claims 15, 31, 34 are objected to because of the following informalities: in claim 15, line 2, "pernninal" should read --perennial--. In claims 31 and 34, line 2 after "such", --treating and/or preventing-- should be added. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 2-3, 5-6, 11-15, 17-18, 20, 22, 27-30, 32, 33, 35, 36, 41-44, 46, 47, 49, 53, 55, 57, 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Claims 2-3 recite the limitation "the geometric mean Tmax" and "the arithmetic mean Tmax", respectively, in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 5-6 recite the limitation "the geometric mean Tmax" and "the arithmetic mean Tmax", respectively, in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 11, 13 recite the limitation "the geometric mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 12, 14 recite the limitation "the arithmetic mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 15 recites the limitation "the allergic reaction" in line 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 17-18 recite the limitations "the geometric mean Tmax" and "the arithmetic mean Tmax", respectively, in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 20 recites the limitation "the geometric mean Tmax" in line 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 22 recites the limitation "the arithmetic mean Tmax" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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12. Claims 27, 29 recite the limitation "the geometric mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

13. Claims 28, 30 recite the limitation "the arithmetic mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 32 recites the limitation "the geometric mean Tmax" in line 1. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 33 recites the limitation "the arithmetic mean Tmax" in line 1. There is insufficient antecedent basis for this limitation in the claim.

16. Claims 35, 36 recite the limitations "the geometric mean Tmax" and the arithmetic mean Tmax", respectively, in line 1. There is insufficient antecedent basis for this limitation in the claim.

17. Claims 41, 43 recite the limitation "the geometric mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

18. Claims 42, 44 recite the limitation "the arithmetic mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 46 is vague and indefinite because it sets forth that the "area under the concentration-time curve of desloratadine is about 32.3 ng.hr/ml. However, claim 45, requires that the area under the concentration-time curve be 56.9ng.hr/ml. Further clarification is respectfully requested.

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20. Claim 46 recites the limitation "the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Moreover, claim 46 is vague and indefinite because the arithmetic mean time to maximum plasma concentration (T_{max}) is about 4.8 hours. However, claim 45 sets forth that the arithmetic mean time to maximum plasma concentration (T_{max}) is about 3 hours.

Further clarification is respectfully requested.

21. Claim 47 recites the limitation "the arithmetic mean AUC(0-24hr)" in line 1. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 49 recites the limitations "arithmetic mean steady state maximum plasma concentration (C_{max})" of 3-OH desloratadine"; "arithmetic mean time to maximum plasma concentration (T_{max}); "Area under the concentration time curve of desloratadine" in lines 1-6.

There is insufficient antecedent basis for this limitation in the claim.

23. Claim 53 recites the limitation "the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Moreover, claim 53 is vague and indefinite because the arithmetic mean time to maximum plasma concentration (T_{max}) is about 4.8 hours. However, claim 52 sets forth that the arithmetic mean time to maximum plasma concentration (T_{max}) is about 3 hours.

Further clarification is respectfully requested.

24. Claim 55 recites the limitation "the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine" in lines 1-2. There is insufficient antecedent basis

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for this limitation in the claim. Moreover, claim 55 is vague and indefinite because the arithmetic mean time to maximum plasma concentration (T_{max}) is about 4.8 hours. However, claim 54 sets forth that the arithmetic mean time to maximum plasma concentration (T_{max}) is about 3 hours. Finally, claim 55 is vague and indefinite because it sets forth that the "area under the concentration-time curve of desloratadine is about 32.3 ng.hr/ml. However, claim 54, requires that the area under the concentration-time curve be 56.9ng.hr/ml. Further clarification is respectfully requested.

25. Claim 57 recites the limitation "the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Moreover, claim 57 is vague and indefinite because the arithmetic mean time to maximum plasma concentration (T_{max}) is about 4.8 hours. However, claim 56 sets forth that the arithmetic mean time to maximum plasma concentration (T_{max}) is about 3 hours. Finally, claim 57 is vague and indefinite because it sets forth that the "area under the concentration-time curve of desloratadine is about 32.3 ng.hr/ml. However, claim 56, requires that the area under the concentration-time curve be 56.9ng.hr/ml. Further clarification is respectfully requested.

26. Claim 59 recites the limitation "the arithmetic mean steady state maximum plasma concentration (C_{max}) of 3-OH-desloratadine" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Moreover, claim 59 is vague and indefinite because the arithmetic mean time to maximum plasma concentration (T_{max}) is about 4.8 hours. However, claim 58 sets

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forth that the arithmetic mean time to maximum plasma concentration (Tmax) is about 3 hours. Finally, claim 59 is vague and indefinite because it sets forth that the “area under the concentration-time curve of desloratadine is about 32.3 ng.hr/ml. However, claim 58, requires that the area under the concentration-time curve be 56.9ng.hr/ml. Further clarification is respectfully requested.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 1-18, 24-28, 31-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handley et al., 5,962,464 and Aberg et al., 5,595,997.

Handley et al. disclose methods for treating allergic disorders such as allergic asthma, urticaria, allergic rhinitis and atopic dermatitis comprising administering a therapeutically effective amount of descarboethoxyloratadine (DCL) otherwise known as desloratadine. The methods also involve treating symptoms associated with allergic rhinitis such as sneezing, lacrimation, rhinorrhea comprising administering an effective amount of DCL. The pharmaceutical compositions containing DCL are administered (in single or divided doses) in an amount of .1mg to less than about 10 mg, preferably ranging from about .1 to 5 mg. Please see the abstract; col. 4, lines 44-50col. 5, lines 30-47; col. 6, lines 13-18; col. 6, lines 55-60.

Aberg et al., disclose methods of treating allergic asthma, allergic rhinitis or urticaria in a human, the methods comprising administering effective amounts of DCL. The amounts of DCL may range from .1 mg to less than about 10 mg, with a preferred dosage ranging from .1 to 5 mg. Please see the abstract; col. 4, lines 34-44; col. 5, lines 48-54; col. 7, lines 33-38; col. 8, lines 19-43.

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Handley and Aberg do not specifically disclose Applicant's claimed geometric mean steady state and arithmetic mean steady state plasma concentrations nor do Handley and Aberg disclose administering DCL twice a day at 2.5 mg; however, absent evidence to the contrary, since Handley and Aberg establish that the efficacy of DCL is dependent upon its dosage, it would have been obvious to one of ordinary skill in the art to further modify the methods of Handley and Aberg such that DCL is administered in an amount and for a time that is effective to optimize its effect on the allergic disorders being treated. Moreover, because both Handley and Aberg disclose administration of desloratadine at a dosage amount claimed by Applicant, the resulting mean plasma concentrations of desloratadine and its metabolite, 3-OH-desloratadine, would have been obvious in the prior art methods.

Finally, with respect to treating a human of 12 years or older, since the both Handley and Aberg disclose treating "humans" in general, one of ordinary skill in the art would reasonably expect human patients of 12 years or older to benefit from the treatment methods of Handley and Aberg.

Allowable Subject Matter

Claims 19-23, 29, 30 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

Conclusion

Claims 1-18, 24-28, 31-59 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Feb. 24, 2002


Cybille Delacroix-Muirheid
Patent Examiner Group 1600